Summary
In recent years, the prices charged for certain types of drugs—referred to as specialty drugs—have become a source of concern for many policymakers. Such drugs typically treat chronic, complex, or rare conditions, frequently have high prices, and may require special handling or patient monitoring.

From 2010 through 2015, specialty drugs accounted for a growing share of new drugs introduced to the market, and they were introduced at much higher prices than nonspecialty drugs. Those factors have contributed to increased spending on prescription drugs in Medicare Part D (Medicare’s prescription drug benefit) and Medicaid. Counting spending by all parties:

- Net spending on specialty drugs in Medicare Part D rose from $8.7 billion in 2010 to $32.8 billion in 2015.
- Net spending on specialty drugs in Medicaid roughly doubled from 2010 to 2015, rising from $4.8 billion to $9.9 billion.

In 2015, brand-name specialty drugs accounted for about 30 percent of net spending on prescription drugs under Medicare Part D and Medicaid, but they accounted for only about 1 percent of all prescriptions dispensed in each program. Because Medicare Part D and Medicaid are two large purchasers of prescription drugs, increases in spending for those drugs could have important implications for the federal budget.

In this report, the Congressional Budget Office examines the net prices paid for specialty drugs and spending on those drugs in Medicare Part D and Medicaid over the 2010–2015 period.1 (In each program, the net price for many drugs is lower than the amount paid to pharmacies, also referred to as the retail price, because of manufacturers’ rebates and other discounts.) Key findings include the following:

- The net prices paid for brand-name specialty drugs are much higher in Medicare Part D than in Medicaid. In 2015, the weighted average net price for 50 top-selling brand-name specialty drugs in Medicare Part D was $3,600 per “standardized” prescription—a measure that roughly corresponds to a 30-day supply of medication—whereas the weighted average net price for the same set of drugs in Medicaid was $1,920. That difference was attributable to much larger rebates in Medicaid than in Medicare Part D.
- Specialty drugs accounted for a growing share of total net drug spending from 2010 to 2015 in both programs, rising from 13 percent to 31 percent of such spending in Medicare Part D and from 25 percent to 35 percent in Medicaid.
- For beneficiaries in the Medicare Part D program who took brand-name specialty drugs, average annual net spending on such drugs per person (in 2015 dollars) roughly tripled over the 2010–2015 period—from $11,330 in 2010 to $33,460 in 2015.

What Are Specialty Drugs?

Researchers and industry stakeholders define specialty drugs in varying ways. Some rely on price alone to define a specialty drug. However, a more useful definition of specialty drugs encompasses a broader set of characteristics that those drugs share, helping to distinguish them from nonspecialty drugs. For this report, CBO identified the specialty drugs that were on the market in 2015 using a definition developed by IQVIA (formerly known as IMS Health).2 By that definition, a specialty drug must treat a chronic, complex, or rare disease and have at least four of the following seven characteristics:

- Cost at least $6,000 per year in 2015,
- Be initiated or maintained by a specialist,
- Be administered by a health care professional,
- Require special handling in the supply chain,
- Be associated with a patient payment-assistance program,
- Be distributed through nontraditional channels (such as a specialty pharmacy), or
- Require monitoring or counseling either because of significant side effects or because of the type of disease being treated.

On the basis of that definition, “orphan” drugs, biologic products, and drugs that treat cancer, multiple sclerosis, and human immunodeficiency virus (HIV) are frequently considered to be specialty drugs.3 However, high-cost drugs used to treat acute conditions are generally not considered to be specialty drugs under IQVIA’s definition. That definition of specialty drugs includes both brand-name and generic drugs, although over 90 percent of net spending on specialty drugs in both Medicare Part D and Medicaid has been on brand-name drugs.

This report focuses primarily on specialty drugs that are purchased from a pharmacy. Such drugs are covered by Medicare Part D and Medicaid’s prescription drug benefit. Some specialty drugs are administered by physicians or other health care professionals. Those drugs are generally covered by Medicare Part B (Medical Insurance) and Medicaid’s medical benefit. However, claims for drugs that are administered by a physician or other health care professional are sometimes submitted under Medicaid’s prescription drug benefit rather than the program’s medical benefit. In 2015, just over 20 percent of net specialty drug spending in Medicaid’s prescription drug benefit was for drugs generally administered by a health care professional. In Medicare Part D, less than 5 percent of specialty drug spending was for such drugs. That difference is one of several factors that cause the composition of specialty drug spending under Medicaid’s prescription drug benefit to differ from that under Medicare Part D.

How Are Prescription Drug Prices Determined in Medicare Part D and Medicaid?

The prices of specialty drugs—and all prescription drugs—are determined very differently in Medicare Part D than in Medicaid. The Medicare Part D drug benefit is delivered by private drug plans, which are mostly chosen by the program’s participants. Under Part D, drug prices are determined primarily through negotiations between those Part D plans and providers (such as pharmacies and drug manufacturers).4 A key factor that helps Part D plans lower drug costs are rebate payments that the plans negotiate with drug manufacturers.

Medicaid beneficiaries can receive drug benefits either through a fee-for-service system or through managed care plans. In either case, the net prices are heavily influenced by two statutory rebates that are linked to prices paid in the private sector. The first statutory rebate is a specified percentage of the average price that manufacturers charge to wholesalers and pharmacies for each drug. (That percentage is greater for drugs that

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2. The list of specialty drugs on the market in 2015 was purchased from IQVIA and is proprietary. (At the time CBO’s analysis was undertaken, 2015 was the most recent year for which data on drug prices and spending were available.)

3. Orphan drugs are approved to treat a health condition that affects fewer than 200,000 people in the United States.

4. A pharmacy-benefit management company such as Express Scripts or CVS–Caremark may administer and manage the drug benefit on behalf of a Part D plan sponsor. In that case, the pharmacy-benefit manager negotiates prices with drug manufacturers and pharmacies.
have larger discounts for private-sector purchasers.) The second statutory rebate must be paid if the average price that a manufacturer charges to pharmacies and wholesalers increases faster than general inflation. This rebate ensures that the net prices manufacturers receive for drugs purchased by Medicaid beneficiaries do not increase faster than inflation. States may also negotiate for supplemental rebates beyond those statutory rebates by using preferred drug lists.

**What Data and Methods Did CBO Use in Its Analysis?**

CBO used beneficiary-level claims data on the entire Medicare Part D population to estimate retail prices and spending on specialty drugs and nonspecialty drugs over the 2010–2015 period. Those data include the total payment at retail prices and the number of units (such as tablets) dispensed for each claim. CBO also used confidential data on the rebates and discounts that Part D plans obtained from manufacturers during that period to estimate net prices and spending by drug.

For Medicaid, CBO used publicly available data on utilization and spending by drug as well as confidential data on statutory rebate amounts over the 2010–2015 period to estimate net prices and spending for each drug. CBO merged the Medicare Part D and Medicaid data with Red Book data, which include drug product characteristics, and with a list of specialty drugs on the market in 2015 that was provided by IQVIA.

For the analysis of Medicare Part D, CBO constructed prices per standardized prescription to control for differences across prescriptions in the number of days a medication was supplied. Because of data limitations, CBO did not construct standardized prescriptions for most of the analysis of prices paid by Medicaid.

The estimates of drug prices and per capita spending presented in this report for 2010 have been adjusted to 2015 dollars to remove the effects of general inflation when comparing those results with estimates for 2015. All estimates of total drug spending are expressed in nominal terms—that is, they have not been adjusted to remove the effects of general inflation. CBO expressed the spending totals in that way to facilitate comparison with budgetary figures published by CBO and other government agencies.

**What Prices Are Paid for Specialty Drugs in Medicare Part D and Medicaid?**

CBO compared the prices paid for 50 top-selling brand-name specialty drugs in Medicare Part D with the prices paid for the same drugs in Medicaid. Retail prices for brand-name specialty drugs are similar in Medicare Part D and Medicaid, but net prices are much higher in Medicare Part D because the rebates are substantially smaller than in Medicaid.

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5. Manufacturers must pay a basic statutory rebate under Medicaid for brand-name drugs that is equal to at least 23.1 percent of the average price manufacturers charge to pharmacies (and to wholesalers that distribute drugs to pharmacies). If the manufacturer offers certain private-sector purchasers a rebate that exceeds 23.1 percent, then the basic rebate received by Medicaid is increased to match that larger private-sector rebate. That linking of Medicaid’s price to the lowest price paid in the private sector can cause certain private-sector purchasers to pay more for some brand-name drugs. Manufacturers of generic drugs are required to pay a statutory rebate equal to 13 percent of the average price that they charge on sales to pharmacies.

6. Medicaid is a joint federal and state program, and states pay a portion of its costs. Those supplemental rebates are not included in CBO’s analysis because data are not available for them by drug. Supplemental rebates negotiated by states represented less than 4 percent of Medicaid drug spending at retail prices in 2015. Medicaid managed care organizations may also negotiate for rebates, but those rebates were not included in this analysis because relevant data were not available.

7. Red Book data are available from IBM Micromedex and include list prices (such as the wholesale acquisition cost) as well as drug characteristics (such as the product name, manufacturer, dosage form, and strength) by National Drug Code. The data also include identifiers that match generic drugs with their brand-name counterparts.

8. CBO defined a standardized prescription as one in which a medication was supplied for a number of days equaling 30 or less. For a prescription in which a medication was supplied for more than 30 days, CBO defined the number of standardized prescriptions as the number of days supplied divided by 30. For example, a prescription for a 90-day supply of medication was defined as three standardized prescriptions.

9. CBO constructed standardized prescriptions in Medicaid for 50 top-selling brand-name specialty drugs to compare the average price of those drugs in Medicaid and Medicare Part D.
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Prices of 50 Top-Selling Brand-Name Specialty Drugs in Medicare Part D and Medicaid in 2015

In Medicare Part D, the weighted average retail price per standardized prescription for 50 top-selling brand-name specialty drugs was $4,380 in 2015, which was similar to the weighted average retail price for the same drugs in Medicaid (see Figure 1).10 (In that comparison, the “mix” of drugs—or the share of total standardized prescriptions attributed to each drug—was held constant for the two programs, using Medicare’s mix.) The average retail price per standardized prescription for those 50 drugs varied greatly, ranging from $250 to almost $43,000.

Net of rebates and discounts, the average price per standardized prescription was nearly twice as high in Medicare Part D as in Medicaid ($3,600 versus $1,920).11 The average net price was much higher in Medicare Part D because the rebates and discounts were much smaller than in Medicaid. Rebates and discounts for those 50 drugs averaged 18 percent of the retail price in Medicare Part D and 56 percent of the retail price in Medicaid.

CBO conducted analogous comparisons for 50 top-selling brand-name nonspecialty drugs in Medicare Part D. The average retail price per standardized prescription for those drugs in 2015 was $300 in Medicare Part D, which was very similar to the average retail price in Medicaid. Net of all rebates and discounts, the weighted average price per standardized prescription for those 50 drugs in Medicare Part D in 2015 was $150—almost three times as much as in Medicaid ($55).

Price Growth for Brand-Name Specialty Drugs in Medicare Part D and Medicaid

CBO used two different approaches to measure the price growth of brand-name specialty drugs between 2010 and 2015. In the first approach, CBO examined the change in the average net price of a prescription over time. In the second approach, CBO used a price index to examine the average annual increase in drug prices over time after they were introduced. The first approach captures increases in the prices of individual drugs over time as

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10. Each drug’s contribution to the weighted average price was proportional to the total number of prescriptions dispensed for the drug under Medicare Part D.

11. Starting in 2011, all estimates of net prices in Medicare Part D in this report include the discount of 50 percent for prescriptions dispensed in a specified phase of the Part D benefit (referred to as the coverage gap) that manufacturers of brand-name drugs were required to provide for beneficiaries who do not receive low-income subsidies.
well as shifts in the mix of drugs used between years. The second approach captures average price increases for individual drugs between consecutive years while holding the mix of drugs constant between years. The first approach yields a much higher estimate of price growth because it incorporates not only the growth captured by the price-index approach but also the shift in use toward higher-priced drugs—including new drugs—during the period examined.

Change in the Average Net Price of a Prescription. The average net price of a prescription for brand-name specialty drugs increased more rapidly from 2010 to 2015 in Medicare Part D than in Medicaid. In each program, that increase was primarily attributable to a shift toward use of higher-priced drugs, including those newly introduced to the market.

From 2010 to 2015, the average net price of a prescription for a brand-name specialty drug increased sharply in both Medicare Part D and Medicaid. In each program, that increase was primarily attributable to a shift toward use of higher-priced drugs, including those newly introduced to the market.

In each program, the increase in the average net price of a prescription for brand-name specialty drugs was largely attributable to a shift toward use of higher-priced drugs—especially new drugs that were introduced after

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12. Those estimates reflect the increase in the average price of a prescription across all brand-name specialty drugs in the two programs. The analysis was not restricted to the 50 top-selling drugs included in Figure 1.

13. If drugs administered by a physician are excluded from the analysis, the average price of a brand-name specialty drug grows a bit more quickly over the period in both Medicaid and Medicare Part D. However, the basic conclusions regarding the comparison between Medicare Part D and Medicaid do not change markedly if physician-administered drugs are excluded from the calculations. With those drugs excluded, the average net price per prescription of a brand-name specialty drug was still much lower in Medicaid than in Medicare Part D in both 2010 and 2015, and the average net price grew at a much slower rate in Medicaid than in Medicare Part D. That analysis is described in greater detail in the working paper that accompanies this report. See Anna Anderson-Cook, Jared Maeda, and Lyle Nelson, Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid: An In-Depth Analysis, Working Paper 2019-02 (Congressional Budget Office, March 2019), www.cbo.gov/publication/55011.
2010. In 2015, the average net price per prescription for those new drugs was $8,680 in Medicare Part D and $4,660 in Medicaid.

**Average Annual Increase in Net Drug Prices Using a Price Index.** Using a price-index approach, CBO estimates that the net prices of brand-name specialty drugs in Medicare Part D grew at an average annual rate of 5.8 percent from 2010 to 2015.\(^{14}\) That increase is far smaller than the 22 percent increase in the average net price of a prescription for brand-name specialty drugs that was cited above for the same period. The price-index approach yields a much slower rate of growth because it does not reflect the increasing use of higher-priced drugs. For example, the price-index approach does not capture the effect of the higher prices at which new specialty drugs were introduced (though it captures any subsequent increases in the prices of those drugs).

After brand-name specialty drugs were introduced to the market, the average net price per prescription in Medicare Part D grew more slowly for such drugs than for brand-name nonspecialty drugs from 2010 through 2015—5.8 percent versus 7.4 percent. However, net prices for brand-name specialty drugs are substantially higher than those for brand-name nonspecialty drugs. Consequently, those estimates of price growth imply that net prices for prescriptions for brand-name specialty drugs increased by an average of about $90 per year from 2010 to 2015, whereas those for nonspecialty brand-name drugs increased by about $10 per year on average.

Because of data limitations, CBO could not apply the price-index approach that was used for Medicare Part D to assess the annual increase in net drug prices over time for Medicaid. However, because of the inflation rebate in Medicaid, CBO expects that the growth of net prices would have been slower in Medicaid than in Medicare Part D.

**What Are the Recent Trends in Spending on Specialty Drugs in Medicare Part D and Medicaid?**

Specialty drugs accounted for a growing share of net drug spending in Medicare Part D and Medicaid from 2010 to 2015. Those increases in spending incorporate the effects of changes in the prices paid for drugs and the quantities purchased. On the basis of past trends and information on recent drug approvals and drugs currently under development, CBO expects that trend to continue.

Specialty drugs are used to treat a similar set of health conditions in Medicare Part D and Medicaid, although the distribution of spending by condition differs between the two programs because of substantial differences in the characteristics of the covered populations. In Medicare Part D, the three conditions that accounted for the most spending on specialty drugs in 2015 were hepatitis C and cancer (each of which accounted for 24 percent of spending on specialty drugs valued at retail prices) and multiple sclerosis (12 percent). In Medicaid, the three conditions that accounted for the most spending on specialty drugs valued at retail prices were HIV (22 percent), hepatitis C (17 percent), and cancer (13 percent).

**Net Spending on Specialty Drugs**

Between 2010 and 2015, net spending on specialty drugs in Medicare Part D increased from $8.7 billion in 2010 to $32.8 billion in 2015, an average annual increase of 31 percent (see Figure 3). Over the same period, net spending on specialty drugs in Medicaid increased from $4.8 billion to $9.9 billion, an average annual increase of 16 percent (see Figure 4).\(^{15}\) During that time, the share of net spending accounted for by specialty drugs rose

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14. The price index incorporated new products as they were introduced to the market. However, the mix of drugs was held constant from one year to the next when estimating the average rate of price growth from one year to the next over the period. CBO computed the average annual increase in prices for each pair of years over the 2010–2015 period. All prices were expressed in 2015 dollars.

15. For each program, the growth in net spending on specialty drugs was partly due to an increase in enrollment. Over the 2010–2015 period, enrollment in Medicare Part D grew at an average annual rate of 7 percent. Because of data limitations, the number of Medicaid beneficiaries who have drug benefits through the program cannot be precisely estimated. Evidence suggests that the number of Medicaid beneficiaries with drug benefits grew by somewhat more than 5 percent per year over the 2010–2015 period. For more details, see Anna Anderson-Cook, Jared Maeda, and Lyle Nelson, Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid: An In-Depth Analysis, Working Paper 2019-02 (Congressional Budget Office, March 2019), www.cbo.gov/publication/55011.
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From 13 percent to 31 percent in Medicare Part D and from 25 percent to 35 percent in Medicaid.

Growth in Net per Capita Spending on Specialty Drugs in Medicare Part D

On a per capita basis and with the effects of general inflation removed, drug spending did not increase very much in Medicare Part D over the 2010–2015 period. That is because the increase in specialty drug spending per beneficiary was largely offset by a decline in spending on nonspecialty drugs. Net per capita spending on specialty drugs in Medicare Part D grew from $330 in 2010 to $830 in 2015 (an average annual rate of increase of 20 percent), whereas net per capita spending on nonspecialty drugs fell from $2,290 to $1,830 (an average annual rate of decrease of 4 percent) (see Figure 5). (As is the case for all estimates of per capita drug spending in this report, those estimates are expressed in 2015 dollars to remove the effects of general inflation.) The growth in net per capita spending on specialty drugs was almost entirely attributable to growth in spending for brand-name specialty drugs, which in turn was the result of an increase in the average net price of a standardized prescription for such drugs.

CBO could not estimate net per capita spending on specialty drugs as precisely for Medicaid because of data limitations. However, the agency was able to determine that net per capita spending on specialty drugs grew at a much slower rate from 2010 through 2015 in Medicaid than in Medicare Part D and that net per capita spending on both specialty drugs and nonspecialty drugs was much lower in Medicaid than in Medicare Part D. CBO estimates that, in 2015, net spending for both specialty and nonspecialty drugs per Medicaid beneficiary with drug coverage was roughly $500. The lower net per capita spending on specialty drugs in Medicaid is the result of lower utilization among the Medicaid population and lower net prices in Medicaid. The lower utilization is attributable to the fact that, on average, people who receive their drug benefits through Medicaid (mostly children and nondisabled adults under age 65) are in better health than those who receive their drug benefits through Medicare Part D (mostly adults age 65 or older and the disabled).

Net Spending on Brand-Name Specialty Drugs Among Users of Such Drugs in Medicare Part D

Average annual net spending per enrollee on brand-name specialty drugs among Part D enrollees who took such drugs increased from $11,330 in 2010 to
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$33,460 in 2015 (in 2015 dollars). Among Part D enrollees who used a brand-name specialty drug and did not receive assistance with their cost sharing (either through the low-income subsidy program or through an employer-sponsored plan), the average annual net spending on such drugs increased fourfold (from $8,970 in 2010 to $36,730 in 2015), and their average out-of-pocket cost for those drugs increased from $1,750 in 2010 to $3,540 in 2015 (all estimates are in 2015 dollars; see Figure 6). Out-of-pocket costs for brand-name specialty drugs accounted for nearly 90 percent of total out-of-pocket costs under Part D for those beneficiaries in 2015. Net spending on specialty drugs and out-of-pocket costs for those drugs varied greatly across beneficiaries.

Some experts have raised concerns about the rapid increase in spending in the catastrophic phase of the Medicare Part D benefit, which in 2015, an enrollee entered after incurring $4,700 in out-of-pocket spending. In that phase of the benefit, Part D plans have limited incentives to manage enrollees’ drug costs because the federal government reimburses the plans directly for about 80 percent of those costs (and beneficiaries pay 5 percent). From 2010 to 2015, the share of drug spending in Medicare Part D (valued at retail prices) that fell within the catastrophic phase of the benefit doubled from 20 percent to 40 percent. Over that period, brand-name specialty drugs accounted for just over 80 percent of the growth in net spending per beneficiary in that phase of the Part D benefit.

What Is the Outlook for Future Spending on Specialty Drugs in Medicare Part D and Medicaid?

On the basis of recent growth in the share of new drugs that are specialty drugs and information about drugs being developed, CBO expects that the share of net spending in Medicare Part D and Medicaid devoted to specialty drugs will continue to grow in the coming years. In recent years, specialty drugs have accounted for a large share of spending in both programs on innovative new drugs (those that have just been introduced to the market and have never before been used in clinical practice). Among innovative brand-name drugs introduced to the market between 2011 and 2015, specialty drugs accounted for about three-quarters of spending in 2015 in both Medicare Part D and Medicaid. Information on drugs recently approved and under development also suggests that specialty drugs will continue to account for a growing share of net spending in the future. For example, about 80 percent of the drugs approved by the Food and Drug Administration in 2017 could be classified as specialty drugs under most definitions.
On a per capita basis and with the effects of general inflation removed, the increase in spending on specialty drugs in Medicare Part D was largely offset by a decline in spending on nonspecialty drugs.

Source: Congressional Budget Office. Spending estimates for 2010 were converted to 2015 dollars using the price index for personal consumption expenditures.

Among Part D enrollees who used a brand-name specialty drug and did not receive any cost-sharing assistance, average annual net spending on such drugs increased fourfold and their average annual out-of-pocket costs for those drugs doubled from 2010 to 2015.

Source: Congressional Budget Office. Spending estimates for 2010 were converted to 2015 dollars using the price index for personal consumption expenditures. The catastrophic phase of the benefit begins after a beneficiary’s out-of-pocket costs exceed a certain threshold; in that phase, beneficiaries pay 5 percent of the costs and the federal government reimburses Part D plans directly for about 80 percent of the costs. In 2015, the threshold was $4,700.
This report was prepared at the request of the Chairman of the House Committee on Ways and Means. In keeping with the Congressional Budget Office’s mandate to provide objective, impartial analysis, the report makes no recommendations.

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CBO continually seeks feedback to make its work as useful as possible. Please send any feedback to communications@cbo.gov.

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